

**REMARKS UNDER 37 CFR§ 1.111**

**Formal Matters**

Claims 1, 12-13, 46, 53, 58, 190-192, 194-211 and 214-223 are pending after entry of the amendments set forth herein.

Claims 203-211 and 214-218 are currently withdrawn from examination.

Claims 2-11, 14-45, 47-52, 54-57, 59-189, 193 and 212-213 have been canceled, without prejudice to the possibility of filing one or more continuing applications directed to the subject matter recited therein.

Claims 1, 12, 13, 46, 53, 58, 190-192, 194-202 and 219-222 were examined.

Claims 1, 12, 13, 46, 53, 58, 190-192, 194-199 and 219-222 were rejected.

Claims 200 and 201 were objected to, but indicated to contain allowable subject matter.

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

No new matter has been added.

**The Office Action**

**Claim Rejected Under 35 U.S.C. Section 103(a) (Vierra et al. in view of Boyd et al.)**

In the Official Action of June 8, 2010, claims 190-192, 194-198, 202 and 219-220 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Vierra et al., U.S. Patent No. 5,749,892 in view of Boyd et al., U.S. Patent No. 5,799,661.

The Examiner asserted that Vierra et al. discloses a device that includes a contact member (15,17) shapeable to engage the surface of a beating heart.

Applicants respectfully traverse. Although Vierra et al. discloses that the surfaces 27 have a curvature selected to approximately conform to the curvature of the outer surface of the heart (column 6, line 65 – column 7, line 1), or, alternatively, may be shaped to conform with other organs or tissue structures (column 7, lines 5-8), it is respectfully submitted that this refers to alternate embodiments and that such shapes are made during the manufacture of the contact members 15,17. It is respectfully

submitted that Vierra et al. fails to disclose contact members 15,17 that are shapeable as claimed. To clarify this distinction, claim 190 has been amended above to clarify that the at least one continuously adjustable contact member is adjustable to assume and maintain a shape that is selectable from a plurality of variable shapes. It is respectfully submitted that Vierra et al. fails to disclose or suggest this capability.

The Examiner further asserted that Vierra et al. discloses a hollow contact member that is capable of being inflated. Applicants respectfully submit that Applicants were unable to find any disclosure by Vierra et al. of either a hollow contact member or a contact member that is inflatable. Applicants respectfully request that the Examiner identify, in the disclosure of Vierra et al., where the support for the Examiner's assertions can be found.

The Examiner further asserted that the contact member of Vierra et al. may comprise a flexible tube 21 that is capable of contacting a surface of the beating heart. Applicants respectfully submit that 21 of Vierra et al. is not a tube. Contrary to the Examiner's assertion, Vierra et al. does not show or describe 21 as a tube, but rather shows and describes 21 as an engaging portion of a foot 11, see Fig. 1 and column 8, lines 38-41.

The Examiner further asserted that Vierra et al. discloses a contact member that is capable of being bent to form a U-shaped configuration. Applicants respectfully traverse. Applicants respectfully submit that Vierra et al. does not disclose this capability. Applicants respectfully submit that Applicants were unable to find any disclosure by Vierra et al. of a contact member that is capable of being bent to form a U-shaped configuration. Applicants respectfully request that the Examiner identify, in the disclosure of Vierra et al., where the support for the Examiner's assertion can be found.

Still further, the Examiner asserted that Vierra et al. discloses a flexible tube that contains a plurality of particles. Applicants respectfully traverse. It is respectfully submitted that Vierra et al. nowhere discloses particles as claimed. Further, Applicants note that on page 4 of the instant Office Action, the Examiner admits that Vierra et al. fails to disclose a granular material. Applicants respectfully submit that Applicants were unable to find any disclosure by Vierra et al. of a contact member comprising a tubular member that contains a plurality of particles or beads as claimed. Applicants respectfully request that the Examiner identify, in the disclosure of Vierra et al., where the support for the Examiner's assertions can be found.

The Examiner admitted that Vierra et al. fails to disclose a contact member that includes a malleable material. The Examiner asserted that Boyd et al. teaches at column 19, lines 60-65, a device having a contact member that comprises a single wire made of a malleable material capable of retaining

its shape. Applicants respectfully traverse. It is respectfully submitted that column 19, lines 60-65 of Boyd et al. describe a snare 214 (See Fig. 36) that is made of a flexible wire or band of highly resilient material. As such, the snare is not malleable, as it does not retain its structure (structural memory) when it is repositioned. On the contrary, due to the resilient nature of the snare, it tends to spring back to its original position after it is deformed, such as by tightening the snare around the object by applying tension. As the tension is released, the snare will tend to resiliently open.

Further, the Examiner asserted that it would have been obvious to modify the device of Vierra et al. to include a contact member comprising a single wire as taught by Boyd et al., since this is well-known in the art.

Applicants strongly traverse. It is respectfully submitted that it would not have been obvious to replace the contact member 27 of Vierra et al. with a snare 214 as taught by Boyd et al. The devices of Vierra et al. and Boyd et al. serve completely different functions, the device of Vierra et al. being used to apply pressure to a surgical site, while the device of Boyd et al. is used to encircle the heart, grasp the heart and retract it. The snare of Boyd et al. would not accomplish the desired function of Vierra et al. Nor is it clear to Applicants how the snare 214 of Boyd et al. could be advantageously combined with the contact surface 27 of Vierra et al. Applicants further submit that it would not have been obvious to apply the resilient wire 214 of Boyd et al. to the device of Vierra et al.

In view of the above amendment and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 190-192, 194-198, 202 and 219-220 under 35 U.S.C. Section 103(a) as being unpatentable over Vierra et al., U.S. Patent No. 5,749,892 in view of Boyd et al., U.S. Patent No. 5,799,661, as being inappropriate.

**Claim Rejected Under 35 U.S.C. Section 103(a) (Vierra et al. in view of Boyd et al. and further in view of Buckman, Jr. et al.)**

Claims 1, 46, 53, 58 and 221 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Vierra et al., U.S. Patent No. 5,749,892 in view of Boyd et al., U.S. Patent No. 5,799,661, and further in view of Buckman, Jr. et al., U.S. Patent No. 5,582,580.

The Examiner asserted that Vierra et al. in view of Boyd et al. disclose the invention substantially as claimed except for a device that includes a means for introducing positive/negative fluid pressure to the contact member. The Examiner did not specifically identify how Vierra et al. is considered to disclose all of the features of claims 1, 46, 58 and 221.

Applicants respectfully submit that neither Vierra et al. nor Boyd et al., whether taken singly or in any proper combination, discloses, teaches or suggests a contact member that is variably shapeable to a plurality of different shapes as claimed, or a contact member formed of a malleable material as claimed, or a contact member comprising a single continuous wire as claimed, or an inflatable contact member as claimed, or an inflatable, flexible tube as claimed, for reasons provided above.

The Examiner asserted that Buckman, Jr. et al. teaches a contact member 82 that is malleable (Fig. 7, column 9, line 28-column 10, line 63) and that it would have been obvious to modify the device of Vierra et al. to include a means for introducing pressure to the contact member, as taught by Buckman, Jr. et al. in order to provide an alternate means of shaping the contact member that allows the contact member to have a plurality of different shapes. In the "Response to Arguments" section of the Office Action on page 5, the Examiner asserted that Buckman, Jr. et al. teaches adding positive and negative fluid pressure to inflate the material, and that once the material is inflated, it is fixed and conforms to the shape of the heart because the flexibility of the material allows it to conform to the shape of the heart.

Applicants respectfully traverse. It is respectfully submitted that it is inconsistent for the Examiner to argue that the material of Buckman, Jr. et al. is fixed, while at the same time argue that it is flexible and able to conform to the shape of the heart. It is respectfully submitted that the shape cannot be both fixed and flexibly conforming. As such, it is respectfully submitted that the Examiner has not set forth a prima facie case of obviousness in this regard.

In view of the above remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1, 46, 53, 58 and 221 under 35 U.S.C. Section 103(a) as being unpatentable over Vierra et al., U.S. Patent No. 5,749,892 in view of Boyd et al., U.S. Patent No. 5,799,661, and further in view of Buckman, Jr. et al., U.S. Patent No. 5,582,580, as failing to set forth a prima facie case of obviousness.

**Claim Rejected Under 35 U.S.C. Section 103(a) (Vierra et al. in view of Boyd et al. and Buckman, Jr. et al. and further in view of Heilman et al.)**

Claims 12, 13 and 222 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Vierra et al., U.S. Patent No. 5,749,892 in view of Boyd et al., U.S. Patent No. 5,799,661, Buckman, Jr. et al., U.S. Patent No. 5,582,580, and further in view of Heilman et al., U.S. Patent No. 5,098,369.

The Examiner asserted that Vierra et al. in view of Boyd et al. and Buckman, Jr. et al. disclose

the invention substantially as claimed except for a contact member that contains a conformable material that is granular, a polymeric, or a gel.

Applicants respectfully traverse. It is respectfully submitted that Vierra et al. in view of Boyd et al. and Buckman, Jr. et al. do not disclose the invention substantially as claimed except for a contact member that contains a conformable material that is granular, a polymeric, or a gel, for at least the reasons provided above with regard to the rejection of claims 1 and 221, since claims 12 and 13 depend from claim 1 and claim 222 depends from claim 221.

The Examiner asserted that Heilman et al. discloses a hollow contact member that contains gel (column 1, lines 15-21) and that it would have been obvious to modify Vierra et al. in view of Buckman, Jr. et al. (the Examiner did not include Boyd et al. here) to include a contact member containing a gel as taught by Heilman et al. since such a device is well known in the art.

Applicants respectfully traverse. Even if it would have been obvious to modify the device of Vierra et al. (as modified by Buckman, Jr. et al.) to include a contact member containing a gel as taught by Heilman et al., which Applicants do not agree that this combination would have been obvious, the resulting combination would still not meet all of the recitations of claims 12, 13 and 222. The contact member taught by Heilman et al. adapted to be easily deformed, thereby reducing the possibility of pressure points occurring on the ventricles surface, see column 5, lines 60-62. As such, Heilman et al. teaches away from providing a contact member that is fixed by application of positive or negative pressure thereto. Further, as noted above, Buckman, Jr. et al. also fails to teach fixing a shape by application of positive or negative pressure, as a shape cannot be simultaneously both fixed and flexible to conform to another shape.

In view of the above remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 12, 13 and 222 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Vierra et al., U.S. Patent No. 5,749,892 in view of Boyd et al., U.S. Patent No. 5,799,661, Buckman, Jr. et al., U.S. Patent No. 5,582,580, and further in view of Heilman et al., U.S. Patent No. 5,098,369, as being inappropriate.

### **Allowable Subject Matter**

Applicants wish to extend their thanks to the Examiner for the indication that claims 200 and 201 contain allowable subject matter. In response thereto, Applicants have submitted new claim 223 that combines the recitations of claims 190 (prior to the above amendment of claim 190), 194, 198 and 201.

Applicants respectfully request the indication of allowance of claim 223 in the next Official Action.

**Conclusion**

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-2653, order number GUID-005CON6.

Respectfully submitted,  
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